DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
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REPLY TO
ATTENTION OF

MCMR-RCQ (70-1n)

24 July 2002

HSRRB Policy Memorandum 2002-02, Version 01

SUBJECT: HSRRB Human Subjects Protection Continuing Education Requirements

1. REFERENCES:

a. 32 CFR 219, *Protection of Human Subjects,* 1 July 1999

b. 10 USC 980, *Limitation on use of humans as experimental subjects*

c. DOD Directive 3216.2, *Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research*, 25 March 2002

d. AR 70-25, *Use of Volunteers as Subjects of Research,* 25 January 1990

e. OTSG 15-2, *Human Subjects Research Review Board*, 11 January 1989

f. Belmont Report

g. *Food and Drug Administration (FDA) Information Sheets: Guidance for Institutional Review Boards and Clinical Investigators*, 1998

h. Office for Human Research Protections (OHRP), *Protecting Human Research Subjects Institutional Review Board Guidebook,* 1993

i. HSRRB Policies and Procedures

j. HSRRB Multiple Project Assurance number DOD 10000

2. HISTORY. This is the first version of HSRRB Policy Memorandum 2002-02. This version is effective 5 August 2002. Details of the history can be found in Appendix A.

3. PURPOSE. The purpose of this policy is to establish human subjects protection continuing education requirements for The Army Surgeon General's Human Subjects Research Review Board (HSRRB) members and support staff.

4. SCOPE. This policy applies to members of all HSRRBs that are established, such as the Army HSRRB and the Joint Army/Navy HSRRB, as well as the USAMRMC

Office of Regulatory Compliance and Quality (RCQ) staff who provide protocol review and other support to the HSRRB.

5. BACKGROUND. DODD 3216.2, paragraph 4.5, requires training and continuing education on protection of human subjects in research for all DOD personnel involved in the conduct, review or approval of research. In addition, 32 CFR 219.107 directs that IRBs (such as the HSRRB) must have an understanding of "applicable law, and standards of professional conduct and practice." AR 70-25, paragraph 2.9a(2) requires that HSRRB members have knowledge of current moral, ethical, and legal standards.

6. POLICY.

a. The importance of training and continuing education of all personnel involved in human subjects research cannot be overstated. Such training is critical to ensure that research is conducted in an ethical manner and that subjects' safety, rights, autonomy, and dignity are protected.

b. All personnel subject to this policy will undergo an initial orientation prior to beginning their relevant duties regarding review of human subjects research. The HSRRB Acting Chairperson has discretion to determine or substitute specific training resources for the basic training and education for personnel. Initial orientation for HSRRB members and HSRRB protocol review support staff includes the following:

(1) Complete all three modules of the OHRP on-line training introduction, "Human Subject Assurance Training" (requires approximately one hour) http://137.187.206.145/cbttng_ohrp/cbts/assurance/login.asp. Incumbents who have not previously taken this or equivalent training (at the discretion of the HSRRB) should complete this exercise as soon as practicable. A certificate of training for each module should be turned in to the Acting Chairperson, HSRRB.

(2) In addition to the above basic training, each candidate member of the HSRRB should read the publication entitled *Protecting Study Volunteers in Research*, by Dr. Cynthia Dunn and Dr. Gary Chadwick. This paperback is comprehensive, but written for new IRB member training. It provides a written test that will be turned in for grading, and a passing score will be stipulated at the discretion of the Acting Chairperson. Also, each candidate HSRRB member should complete the DHHS National Institutes of Health on-line training entitled, "Human Participant Protections Education for Research Teams," at http://cme.nci.nih.gov. A certificate of completion should be turned in to the Acting Chairperson, HSRRB.

c. These introductory training materials provide appropriate general information about IRBs, research ethics, and federal regulations. While DOD-sponsored research is subject to much of the same federal requirements, and ethical review of DOD research is similar to non-DOD research, the DOD, Army, USAMRMC, and the HSRRB have specific processes and policies that are not always analogous to the processes and policies of other institutions.

d. Individuals reviewing and/or approving human subjects research submitted to the HSRRB are responsible for acting in accord with specific laws, regulations, policies, procedures, and guidance applicable to the HSRRB. The required familiarity will be achieved by self study of these documents and by other training experiences. The Acting Chairperson of the HSRRB will furnish updated printed sets to all personnel, above, whose activities are governed by these materials. These laws, regulations, policies, procedures, and guidance are also maintained at the USAMRMC website at http://mrmc-www.army.mil/ (under "Medical Research & Development" click on "Regulatory Compliance and Quality Assurance" then click on "Human Subjects Protection").

e. After completing the introductory training, each prospective HSRRB participant (member or protocol review support staff) must also attend at least one meeting, with read-ahead materials, as an observer before becoming a voting member or HSRRB contributor.

f. The Acting Chairperson of the HSRRB or another senior HSRRB member will meet individually with each new member prior to their assumption of HSRRB duties, to:

(1) Introduce training materials, self-study requirements, and expectations therewith;

(2) Discuss the roles of voting members, including the prospective member's own expertise and the overall responsibilities of the HSRRB, alternates, primary reviewers, and scientist reviewers;

(3) Encourage members and alternates to participate actively in HSRRB meetings;

(4) And orient new members and alternates about attendance, review, discussion and presentation responsibilities and schedules.

g. Additional authoritative, specific guidance on IRB matters is available on-line:

(1) FDA Information Sheets, updated in 1998, provide guidance for IRBs, at http://www.fda.gov/oc/ohrt/irbs/default.htm. This is a good resource for general human subjects research protection requirements and FDA requirements of IRBs.

(2) The OHRP IRB Guidebook is a useful resource, and is located at http://ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm. Other specific guidance is available throughout http://ohrp.osophs.dhhs.gov.

h. HSRRB members and support staff subject to this policy must undergo annual continuing education as provided and directed by the Acting Chairperson of the HSRRB.

(1) For HSRRB members, attendance at an annual meeting of the Public Responsibility in Medicine and Research (PRIM&R) within two years of HSRRB membership is recommended. This premier IRB professional meeting is especially valuable for new IRB members. Early planning and registration at www.primr.org for the meetings is necessary, as attendance is growing but still limited.

(2) A subscription to *IRB*, a journal devoted to ethics of human subjects protection, will be provided to each HSRRB member and alternate.

(3) At each HSRRB meeting, there will be approximately 15 minutes of continuing education activities, to be comprised of one or more of the following, as directed by the Acting Chairperson of HSRRB:

(a) A brief discussion of a recent article in *IRB*, designated in advance, or of a recent newspaper or journal article about human subjects research, distributed to meeting attendees in advance;

(b) A brief presentation by invited local or visiting experts on scientific or administrative IRB issues not adequately covered by the available expertise of the members, e.g., epidemiology, genetics research, HIPAA requirements, vaccine outcomes, applicable state laws, etc.

(c) In rotation, HSRRB members will review, present, and lead discussions on ethics and IRB issues, selected from a list of topics and dates drawn up by the Acting Chairperson of the HSRRB: e.g., dealing with impaired decision making capacity, subject privacy, the use of placebos, international research, etc.

(d) Brief presentations of highlights and trends from the PRIM&R sessions by members who had attended.

Whenever possible, available HSRRB alternates and designated support staff should attend these continuing education sessions during convened HSRRB regular meetings.

(4) Annual off-site conferences (1 - 2 days) will be held for the primary and alternate members and designated support staff of the HSRRB, on a subject relevant to IRB issues, to be selected by the Acting Chairperson of the HSRRB. Appropriate topics include in depth exploration of specific issues raised in the monthly continuing education sessions, and/or elaboration of new IRB policies.

7. RESPONSIBILITIES.

a. The HSRRB Acting Chairperson:

(1) must ensure that HSRRB members are adequately trained. The Acting Chairperson will determine the initial training and continuing education that is required for HSRRB members. The HSRRB Acting Chairperson must also complete such training.

(2) will determine which HSRRB support staff must complete training and education, and will determine the training and education requirements for support staff, including the protocol review staff.

(3) will determine what training is appropriate for the Commanding General, USAMRMC.

b. The HSRRB will maintain records of training and education of its Acting Chairperson and members, support staff, and Commanding General.

Encl

Julie K. Zadinsky
JULIE K. ZADINSKY
COL, AN
Acting Chair, Human Subjects
Research Review Board

MCMR-RCQ
SUBJECT: Policy Memorandum 2002-02, HSRRB Human Subjects Protection Continuing Education Requirements

RECOMMEND APPROVAL/~~DISAPPROVAL~~

DATE: 30 Jul 02
LESTER MARTINEZ-LOPEZ
Major General, MC
Chair, Human Subjects
Research Review Board

APPROVED/~~DISAPPROVED~~

FOR THE SURGEON GENERAL:

DATE: 3 Aug 02
KENNETH L. FARMER, JR.
Major General
Deputy Surgeon General

APPENDIX A

HSRRB Policy Memorandum History

Version Number: 01

Version Date: 24 July 2002

Effective Date:

Reason for Revisions: This is the initial policy.

Detailed List of Changes: N/A